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(54) Title: SOFT AND CHEWY COUGH AND COLD RELIEF COMPOSITION

(57) Abstract

A cough and cold composition is soft and chewy and delivers one or more actives, including zinc and menthol, to alleviate symptoms.

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SOFT AND CHEWY COUGH AND COLD RELIEF COMPOSITION

Field of the Invention -

The present invention relates to a soft and chewable cough and cold relief composition, and specifically to a storage-stable formulation containing one or more active ingredients which provide rapid and substantial relief from cough and cold symptoms.

Background of the Invention -

Medications for cough and cold relief are known in the art. A large number of these are available as over-the-counter preparations in the form of cough drops, lozenges, chewing gums, and other confectionery-based formulations. Many of these are hard and sugary, to be placed in the mouth so that the action of saliva can release the active ingredients over the course of several minutes.

What is therefore needed in the art is a composition containing one or more cough and cold actives which is soft and chewable, and which releases the active(s) quickly to promote rapid relief as well as sustained relief thereafter.

Summary of the Invention -

These and other objects of the invention are provided in the form of a soft and chewable, storage-stable confectionery composition which contains one or more encapsulated active ingredients to provide relief from cough or cold symptoms. Active ingredients can include antitussives, antihistamines, nasal decongestants and analgesics.

The composition of the invention, while storage stable for extended periods, dissolves quickly in the mouth upon chewing to release the active ingredients. The composition of the invention is easily pliable inside the mouth, and can be administered like a soft nougat-type formulation.

Detailed Description of the Preferred Embodiments -

In at least one embodiment of the invention there is provided a confectionery-type composition which provides active ingredients for relief from many cough and cold symptoms. Unlike other formulations known in the art, the composition herein provided is

soft, chewable and dissolves quickly in the mouth. Sufferers of cold and flu symptoms, as well as other nasal/respiratory conditions, attain prompt relief which lasts for an extended period. Such conditions can include stuffy head, runny nose, nasal and sinus congestion and the like.

The composition provides as a first component at least one member selected from the group consisting of saccharide-based material. Examples include the mono-, di-, tri- and polysaccharides available in the food and confectionery industry, including oligomers, and oligosaccharides, as well as mixtures of any of the foregoing. As non-limiting examples, sugars such as sucrose, glucose (corn syrup), dextrose, invert sugar, fructose, and mixtures thereof may be useful. Less or non-sweet sugars and polysaccharide material such as maltodextrin, corn syrup solids and polydextrose may also be utilized. In certain embodiments of the invention, "sugar-free" or "non-sucrose" materials, or even "non-saccharide" compounds, either in whole or in part, may be especially desirable. Thus, other compounds may be selected from the group consisting of aspartame, acesulfame, saccharin and its various salts such as the sodium and calcium salts, cyclamic acid and its various salts, dipeptide sweeteners, chlorinated sugar derivatives such as sucralose, dihydrochalcone, glycyrrhin, Stevia rebaudiana (Stevioside), and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, hexa-resorcinol and the like, including mixtures of any of the foregoing, are contemplated for use herein. Hydrogenated starch hydrolysate, (lycasin), and the potassium, calcium and sodium salts of 3,6-dihydro-6-methyl-1-1,2,3-oxathiazin-4-on3-2,2-dioxide are also within the scope of the invention as a saccharide material.

Especially preferred saccharide-based materials include sucrose, corn syrup solids, maltodextrin, xylitol and aspartame. Aspartame is desirable as a non-saccharide sweetener. The saccharide-based component will typically comprise about 25 to 99.5% of the final formulation (unless otherwise stated, all weight percentages herein are based on the total weight of the final composition). More typically, the composition will contain about 40 to 95%, and even more desirably about 70 to 90% of saccharide-based material.

It is especially desirable that the saccharide-based component be in substantially dry form, that is, without any added liquid. In this way, it should bind substantially more easily with the binding component, hereinafter described.

In admixture with the saccharide-based component is a food-grade binding component. The binding component is one which is used to mix and functionalize the other ingredients so as to provide a cohesive final mass. The binding material or binder is selected from materials in the art with demonstrative ability to bind and hold the other ingredients. The binding material may be selected from the group consisting of food grade gums, carrageenan and proteinaceous material, as well as mixtures thereof. Especially preferred are gum arabic, gum acacia and gelatin. Water is also included as part of the binding material. When added, water will comprise about 30 to 70% of the binding material, and more preferably, be included as about 40 to 60% thereof. When liquefied with water, the binding component acts to imbibe and absorb the dry saccharide-based component. Also preferably included as part of the binding material is a humectant or wetting agent. Polyols are preferred for this purpose; in particular, glycerol. Glycerine is also contemplated. It is desirable that the binding material contain about 25 to 45% of humectant, more preferably about 30 to 40%.

Either or both of the saccharide-based and binding components may be provided in shearform matrix by means of flash-flow processing. Either or both of the saccharide-based component and the binding component may be admixed together using flash-flow processing. This method of processing helps to ensure intimate admixture of all ingredients, thereby providing shearform matrix attributes. Flash-flow processing and apparatus is described in U.S. Patent Nos. 5,236,734, 5,238,696, 5,518,730, 5,387,431, 5,429,836, 5,549,917, 5,556,652, 5,582,855 and most recently, 5,834,033. For example, U.S. Patent No. 5,380,473 sets forth a process in which the temperature of a nonsolubilized feedstock carrier is increased to a point where it will undergo internal flow, followed by ejecting a stream of the feedstock and then subjecting it to disruptive fluid shear force which separates it into separate parts or masses which have a transformed morphology. Also disclosed in the '473 reference is an apparatus with a high pressure nozzle for changing the morphology of the feedstock. In U.S. Patent No. 5,834,033, a spinner head includes a base and a cover spaced apart from the base. A plurality of discrete spaced apart elongate heating elements are positioned between the base and the cover and define a chamber for accommodating feedstock material therein. The chamber is spun and the feedstock material is heated and is expelled through the spaces between the heating elements. Feedstock engagement surfaces are positioned in alignment with each of the

spaces between the heating elements so as to engage the expelled feedstock to alter the direction of travel of the expelled product. Other means to provide shearform matrix includes high and low shear processing using such mixers as Littleford, Hobart and Guittard mixers, including mixers with paddle type blades and those which provide propeller-type, highly localized and focused mixing action.

Active ingredients are those known in the pharmaceutical industry, especially the over-the-counter pharmaceutical industry, which cure, relieve, alleviate or lessen one or more symptoms associated with ailments like colds, flu, fevers, certain allergies and cough, etc. Symptoms can include stuffy head, congestion, sinus pressure, aches, pains, sore throat, fever, etc. Active ingredients to help relieve these symptoms can therefore include various antitussives, antihistamines, nasal decongestants and analgesics. Other actives include those which may be recognized as preventive in nature as well. All of the foregoing are therefore to be encompassed by the term "cough and cold active". More specifically, menthol, eucalyptol or other eucalyptus derivative, and zinc are especially contemplated for inclusion in the product of the invention. Zinc ion salts are particularly preferred. Zinc acetate dihydrate is just one example of a suitable zinc compound. Other broad classes of compounds with applicability herein may also be included as actives in the final composition. For example, nutraceutical substances derived from plant material with some demonstrated ability to relieve cough and cold symptoms may also be included. The active ingredient(s) together will comprise from about 0.1 to 40% of the final cough and cold formulation. More desirably, one or more actives will make up about 0.5 to 5% of the final composition. On an actual weight basis, the active may be provided according to recommendations known in the art. For example, published guidelines from the U.S. Food & Drug Administration, or other industry sources, may be utilized to provide an optimal dosing level.

One or more of the active ingredients are preferably provided in the form of encapsulations. An encapsulated active ingredient matrix seems to provide for more content uniformity in the final composition. Encapsulation may also impart a greater degree of stability to the cough and cold actives during relatively prolonged periods of commercial storage. Encapsulation may be accomplished by methods known in the art. In order to effectively encapsulate the active ingredients, one or more food-grade materials are employed as processing aids. These edible materials can include oleaginous substances

(fats and oils), as well as certain waxes, saccharides, phosphatides, proteins and other non-toxic polymeric material, especially those with emulsifying properties. Highly suitable encapsulation processing aids are preferably oleaginous material and any one or more oleaginous food and pharmaceutical grade materials may be utilized for this purpose. It is believed that the encapsulating material surrounds and enrobes tiny individual particles of the active substance, thereby creating a matrix of several thousand or more individually enrobed particles once combined into the final confectionery nougat-like composition. Especially volatile active substances are further rendered less volatile as a result of encapsulation.

Especially suitable oleaginous encapsulating material includes various food-grade oils and fats available in the industry. Of these, those with emulsifying properties are particularly preferred. Vegetable and animal oils and fats may be utilized for this purpose. Stearine, for example, may be utilized as an encapsulating agent, while certain mono- and diglyceride-based fat products are also efficacious. Canola, cottonseed and soybean oils may be preferred as well in certain embodiments. Also useful is one or more medium chain triglyceride (MCT) oils, as well as other mono-, di- and triglyceride-based fatty acid oils. Waxes such as carnauba are also particularly useful in certain embodiments. Phosphatides such as lecithin are highly desirable as well. When utilized, the encapsulating material itself will typically comprise about 0.1 to 10% of the final confectionery, cough and cold formulation, and more desirably, will be within the range of from about 0.5 to 5% thereof. It is especially preferred that the encapsulating material comprise about 0.5 to 3% of the composition. Other material may be utilized as plasticizers, thickening agents or absorbents in the encapsulation. Certain polymeric materials are especially useful for this purpose. These include certain cellulosic materials, including hydroxyalkylcellulosic and hydroxyalkylalkylcellulosic polymers. Of these, hydroxymethyl-, hydroxyethyl-, hydroxypropyl- and hydroxypropylmethylcelluose (HPMC) are desirable. Other material such as silicon dioxide or silica gel may be utilized as well as, for example, to provide bulk.

Low and high shear mixing apparatus are especially useful for preparing encapsulations of the active ingredient(s). Spray-drying and extrusion methods are also available and are known in the art. Other highly suitable methods include flash-flow processing as described in U.S. Patent Nos. 5,236,734, 5,238,696, 5,518,730, 5,387,431,

5,429,836, 5,549,917, 5,556,652, 5,582,855, and 5,834,033. The heretofore described method set forth in U.S. Patent No. 5,380,473 is especially useful for preparing encapsulations. The method of the '473 reference helps to provide a microparticulate dispersion of the active ingredient throughout the entire matrix of the final composition, when the active is mixed with the saccharide and binding components to form the final composition. A combination of any of the foregoing encapsulation methods is also within the scope of the invention. In addition to the active cough and cold ingredient(s), it is also contemplated that any of the other ingredients constituting the final formulation, including any flavorants, hereinafter described, be encapsulated as well.

Other ingredients which may be included as part of the final cough and cold formulation include certain flavorants. These may be selected from any of the industry-available natural and synthetically-derived food and pharmaceutical flavors in whatever form. Especially preferred are those materials which impart a cooling and/or vaporizing sensation upon ingestion. As non-limiting examples, peppermint, spearmint, wintergreen, cinnamon, menthol and menthone flavors, oils and derivatives are desirable. Other flavors, such as fruit flavors, and in particular, cherry flavor, are also desirable. Flavorants will typically comprise from about 0.1 to 5% of the final formulation.

Trace amounts of natural and synthetic colorants can also be utilized to enhance the aesthetic appeal of the final confectionery.

All the foregoing ingredients constituting the cough and cold confectionery may be admixed together using methods known in the art. The heretofore stated methods of flash-flow processing, high shear mixing and low shear mixing are contemplated. In particular, high and low shear mixing methods are especially desirable. Littleford, Guittard and Hobart-type mixers may be utilized for this purpose.

The composition of the invention is highly storage stable since encapsulation of the active ingredients helps to prevent their premature dissipation upon exposure to ambient atmospheric conditions.

EXAMPLES -

The following example illustrates a preferred formulation of the product of the invention, but should not be construed as limiting the scope thereof.

Example 1 -

A soft, chewy confectionery formulation was prepared having the following composition:

Ingredient	Weight Percentage (%)
Saccharide Component*	83.5
Binding Component**	11.8
Encapsulation Material	1.7
Active Ingredients	2.67
Aspartame Sweetener	0.1
Flavor	0.2
Color	Trace

* Saccharide Component - included a mix of sugar (48%), high maltose corn syrup solids (18%), maltodextrin (15%) and xylitol (2.5%).

** Binding Component - included gelatin (2.25%), gum arabic (0.60%), glycerine (3.70%), water (5.25%) and sucrose super-saturated solution.

Active Ingredients were zinc acetate dihydrate (0.34%, preferred range of about 0.1 to 0.6%) and menthol (2.33%, preferred range of about 0.5 to 10%). Encapsulation materials for the actives included MCT oil (1.0%) and lecithin (0.70%). The actives were encapsulated using a combination of Hobart and Littleford mixers. All the ingredients were then admixed together using low shear mixing apparatus. The batch was then cut into approximately 5.3 gram serving sizes. The formulation was soft and chewy and provided an almost instantaneous cooling and vaporizing action.

Thus, while there have been described what are primarily believed to be the preferred embodiments, those skilled in the art will appreciate that other and further changes and modifications can be made without departing from the true spirit of the invention, and it is intended to include all such changes and modifications within the scope of the claims which are appended hereto.

CLAIMS:

1. A soft and chewable confectionery composition, comprising in admixture:

a) a saccharide-based component in an amount of about 40 to 95%;

b) a binding component in an amount of about 0.5 to 5%; and

c) at least one encapsulated active ingredient which is suitable to alleviate one or more cough or cold symptoms.

2. The composition of Claim 1, wherein said active ingredient comprises at least one member selected from the group consisting of antitussives, antihistamines, nasal decongestants and analgesics.

3. The composition of Claim 1, further comprising at least one member selected from the group consisting of flavorants and sweeteners.

4. The composition of Claim 2, wherein said active ingredient comprises at least one member selected from the group consisting of menthol and zinc.

5. The composition of Claim 4, wherein said active ingredient is encapsulated with oleaginous material.

6. The composition of Claim 5, wherein said oleaginous material comprises at least one member selected from the group consisting of MCT oil and lecithin.

7. The composition of Claim 6, wherein said binding component comprises at least one member selected from the group consisting of gelatin, food grade gums and carrageenan.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/00 A61K9/16 A61P11/02 A61P11/14 A61P29/00
A61P37/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	EP 0 788 746 A (MONDO BENI CO LTD ;YASUI CONFECTIONERY CO LTD (JP)) 13 August 1997 (1997-08-13) page 2, line 40 - line 46; claim 1; table 1	1-7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

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